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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,969	11/18/2003	James D. Ralph	F-305	5368

51640 7590 05/15/2006

SPINE MP
LERNER, DAVID, et al.
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/715,969	Applicant(s) RALPH ET AL.	
	Examiner Javier G. Blanco	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 24, 2006 has been entered.

Response to Amendment

2. Applicants' cancellation of claims 8-21 in the reply filed on April 24, 2006 is acknowledged.
3. Applicants' addition of claims 22-44 in the reply filed on April 24, 2006 is acknowledged.

Claim Objections

4. Claim 42 is objected to because of the following informality: please delete "at least" (line 3, first instance). Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding each of claims 38 and 39, the limitation "the outer surface" (see claim 38, line 3; claim 39, line 2) lacks antecedent basis.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 22-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. **11/037,921**. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the two applications claim an intervertebral spacer device comprising an arched strip spring having lateral ends connected/attached to a first plate, and a peak/central portion/curvate volume connected/attached to a second plate. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 22-24 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ratron (US 5,676,702 A).

As seen in Figures 1-5, Ratron discloses an intervertebral spacer device comprising: (i) a first plate (first plate 11) having a first inner surface and a first outer surface, (ii) a second plate (second plate 10 + partition 12; see column 1, lines 66-67) having a first inner surface and a first outer surface, wherein the inner surface of the first plate opposes the inner surface of the second plate, and (iii) at least one arched strip spring (partition 13 + partition 14) disposed between the inner surfaces of the first and second plates, said at least one arched strip spring having flat

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opposing ends coupled with said first plate, and a curvate central portion (see column 2, lines 5-18) between the opposing ends that is coupled with said second plate.

Response to Arguments

11. Applicants' response, filed April 24, 2006, did not present/include arguments against Ratron (US 5,676,702 A). Claims 22-24 disclose the same subject matter of cancelled claims 8-11.

12. Claims 22-26, 31-34, and 40-43 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pisharodi (US 6,610,093).

As seen in Figures 3, 4B, and 4C, Pisharodi discloses an intervertebral spacer device comprising: (i) a first plate (**first interpretation:** disk 26D; **second interpretation:** either one of upper bracket 22 or lower bracket 24) having a first inner surface and a first outer surface, (ii) a second plate (upper bracket 22 or lower bracket 24) having a first inner surface and a first outer surface, wherein the inner surface of the first place opposes the inner surface of the second plate, and (iii) at least one arched strip spring (leaf-type springs 64B; see column 3, lines 40-52; column 4, lines 51-63) disposed between the inner surfaces of the first and second plates, said at least one arched strip spring having flat opposing ends coupled with said first plate, and a curvate central portion between the opposing ends that is coupled with said second plate.

Response to Arguments

13. Applicants' response, filed April 24, 2006, did not present/include arguments against Pisharodi (US 6,610,093). Claims 22-26, 31-34, and 40-43 disclose the same subject matter of cancelled claims 8-13, 20, and 21.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 28, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 6,610,093) in view of Bryan et al. (US 6,156,067).

Pisharodi discloses the invention as claimed (see 102(e) rejection) except for particularly disclosing the use of threaded fasteners. However, this is already known in the art. For example, Bryan et al. disclose (see Figures 6, 9, and 10) the subject matter of using threaded fasteners (e.g., screw 362; screw 92) in order to attach a spring (e.g., endoprosthetic vertebral body 320; ligament 250) to intervertebral plates (see plates 322, 324). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of using threaded fasteners, as taught by Bryan et al., with the at least one arched strip spring of Pisharodi, in order to attach said spring to intervertebral plates.

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14. Claims 29, 30, 38, 39, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 6,610,093) in view of Baumgartner (US 5,370,697 A; cited in Applicants' IDS).

Pisharodi discloses the invention as claimed (see 102(e) rejection above). Although Pisharodi discloses the external plate surfaces as convex to match the contour of the opposing bone surfaces, and the desirability of tissue ingrowth, he/she did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Baumgartner discloses an intervertebral spacer device comprising: (1) a first plate (upper plate 2) having an exterior surface (see Figure 1a); (ii) a second plate (lower plate 3) having an exterior surface (see Figure 1a); and a mesh (e.g., wire mesh 44; see Figures 1a and 5; see column 3, lines 53-59) capable of being deflected/moved (i.e., "deflectable"; "movable") under load and is non-congruent with the one of said exterior surfaces when in an undeflected state (see Figures 1a and 5). As shown in Figures 1a and 5, the exterior surface of the one of said exterior surfaces includes a substantially flat region, and the wire mesh overlies and is spaced from said substantially flat region in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device which external plate surfaces include a substantially flat region, and a deflectable wire mesh overlying and spaced from said substantially flat region, as taught by Baumgartner, with the intervertebral spacer device of

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Pisharodi, in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

15. Claims 27 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 6,610,093) in view of Ralph et al. (US 5,989,291; cited in Applicants' IDS).

Pisharodi discloses the invention as claimed (see 102(e) rejection) except for particularly disclosing the use of a threaded fastener to connect the peak to the first plate. However, this is already known in the art. For example, Ralph et al. disclose (see Figures 7-9) the subject matter of using a threaded fastener (e.g., screw 205) in order to attach the peak/central portion of an arched spring (e.g., spring 230) to a first intervertebral plate (e.g., plate 200). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of using a threaded fastener, as taught by Ralph et al., with the at least one arched strip spring of Pisharodi, in order to attach the peak/central portion of an arched spring (e.g., spring 230) to a first intervertebral plate.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Korzh et al. (SU 1560184), and Schug et al. (EP 0 599 419).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

May 9, 2006

A handwritten signature consisting of the letters 'JGB' in a stylized, cursive font.A handwritten signature in cursive script.

David H. Willse
Primary Examiner